# Best Practice
# Statistical Quality Control

**SCOPE OF THIS PRACTICE.** This document provides information that may be applied during the implementation of a Statistical Quality Control (SQC) program that includes process control and sampling techniques. This information may be used by the production approval holder and its suppliers, hereafter referred to as the manufacturer. SQC programs are considered part of the manufacturer's overall quality system. However, there is no regulatory requirement for establishing an SQC program, and establishing such a program based on the information provided in this document is voluntary. The Federal Aviation Administration (FAA) encourages such a program to help reduce nonconformances, process variation, scrap, and to improve product quality.

**BACKGROUND.** SQC is generally described as the control of product quality by statistical methods. Various techniques developed by mathematical statisticians for the analysis of data may be used in the control of product quality. This Best Practice addresses two separate but related techniques, Statistical Sampling and Statistical Process Control (SPC). These SQC techniques are defined in the next section of this document. This document does not detail the application of control charts or the development of sampling plans. However, it provides information for overall statistical sampling practices and SPC.

**DEFINITIONS.** The following definitions are used within the context of this document and may not be the same as similar terms used in other documents or applications:

**a. Inspection by Attributes.** A method of inspection whereby either the unit of product is classified simply as "defective" or "non-defective" or the number of nonconforming characteristics (defects) in the product is counted with respect to a given requirement(s).

**b. Characteristic.** A product feature that requires an inspection in order to show conformance to engineering design specifications. The most commonly specified characteristic classifications are critical, major, and minor. These classifications are traditionally defined as follows:

(1) Critical Characteristic – a characteristic based on judgement and experience that, if not met, would cause an unsafe condition.

(2) Major Characteristic – a characteristic other than critical that, if not met, would reduce the usability of a product and could cause an unsafe condition.

(3) Minor Characteristic – a characteristic that, if not met, would not reduce the usability of a product and would have no adverse effect on safety.

**c. Statistical Process Control.** A method used for measuring, analyzing, detecting, and controlling process variation. This method may include the following measurable quality characteristic control charts:

- *X*-bar and *R* chart, the average and range
- *X*-bar and *s* chart, the average and standard deviation
- *p* chart, the number rejected
- *c* chart, the number of non-conformities per unit

**d. Statistical Quality Control.** The application of statistical techniques (SPC and Statistical Sampling) to control a product characteristic to ensure it meets product specifications or the engineering design specifications.

**e. Statistical Sampling.** A method of inspection performed throughout the manufacturing process, according to sampling acceptance plans, and based on the laws of probability. Statistical sampling inspects defined characteristics on a portion of a lot to statistically determine if the entire lot is acceptable.

**f. Inspection by Variables.** A method of inspection whereby a measurement is made to determine and record the numerical magnitude of a characteristic under consideration.

**SQC PROGRAM.** An SQC program should be part of the overall quality system, approved by quality management, and documented with a detailed written description of all key elements of the program. Each manufacturer is unique with regard to size, facilities, personnel, resources, and methods of operation; therefore, different SQC techniques may be appropriate. The program should be tailored to the manufacturer's product and associated processes, and may include SPC for process control and statistical sampling for inspection and acceptance.

**STATISTICAL SAMPLING.** Statistical sampling plans may be used for the inspection of critical, major, and minor characteristics. When properly implemented, statistical sampling provides adequate assurance that products conform to the engineering design specifications. Statistical sampling techniques should be outlined in the manufacturer's statistical sampling inspection plan. Sampling plans should be based on valid industry practices (e.g., ANSI/ASQC Z1.4, ANSI/ASQC Z1.9) and should not allow for the acceptance of nonconforming characteristics. Sampling plans should be clearly documented in the quality program and should include the following criteria:

**a. Identifying Characteristics.** An essential step in the implementation of statistical sampling is to ensure that each characteristic being considered is identified, evaluated, and properly classified. Classification determines the applicable accept/reject criteria and lot sample as specified in paragraph c. below, based on the effect specific characteristics may have on safety. The most common characteristic classifications are critical, major, and minor.

**b. Sampling Plan Criteria.** Sampling plans allow a lot, batch, or group of product to be accepted based on the inspection of a portion of that lot, batch, or group. To maintain confidence in the ability to predict the overall quality of the product, based on the inspection of only a portion of those units of product, the following criteria should be included in the manufacturer's sampling plan:

(1) The lot, batch, or group should be homogeneous. Each lot or batch should consist of units of product of the same characteristic classification (i.e., critical, major, or minor), type, grade, class, composition, etc.

(2) The lot, batch, or group should be clearly identified and segregated throughout the process of sampling inspection.

(3) The lot, batch, or group should be manufactured under the same data and conditions, at approximately the same time.

(4) The process(es) used to manufacture the product should be documented, controlled, repeatable, and consistent.

(5) The sample size should be selected with respect to the size of the lot, batch, or group. The sample size should also be statistically valid, where the probability of discovering nonconforming product equates to an acceptable level of quality. The criteria/rationale for determining the sample size should be identified and documented prior to the selection of the sample.

(6) The sample should be randomly selected from the lot, batch, or group, with each unit having the same probability of being selected.

**c. Acceptance/Rejection Criteria.** Prior to the use of sampling plans for the inspection of any characteristics, the manufacturer should ensure that the processes used to manufacture the product result in characteristics that are in conformance with engineering design specifications.

The manufacturer is responsible for ensuring that its product conforms to the engineering design specifications. Therefore, the use of acceptance/rejection criteria in sampling tables where the number of defective characteristics in the lot sample is greater than zero should not be used for acceptance inspection.

In the event that any critical or major characteristics are found to be nonconforming in the lot sample, the entire lot, batch, or grouping should be withheld. Prior to acceptance, the entire lot should be subjected to 100 percent inspection (screened) of that characteristic in order to ensure that there are no other parts in the lot that are nonconforming. All nonconforming parts should be processed in accordance with the manufacturer's approved material review procedures.

When minor characteristics are found to be nonconforming in the lot sample, the entire lot, batch, or grouping should be withheld and dispositioned in accordance with the manufacturer's approved material review procedures.

**d. Conformity to the Engineering Design Specifications.** Regardless of the use of statistical sampling, the manufacturer is responsible to ensure that all parts and products conform to the engineering design specifications. The manufacturer should withhold and disposition through an approved material review process, all parts or products that do not conform to the engineering design specifications as indicated in paragraph c. above.

**e. Review of Statistical Sampling Programs.** Statistical sampling programs that are to be used for the purpose of inspection/acceptance are considered part of the manufacturer's overall quality system. The statistical sampling plans should be reviewed periodically and revised as appropriate to ensure that they are current and operational.

**STATISTICAL PROCESS CONTROL.** When properly implemented, SPC is a continuous verification of the manufacturing process to which it is applied, and may help to reduce defects in the specific characteristics being monitored. Although SPC should not be used for product acceptance, it may be implemented for two primary purposes:

- monitor, detect, and subsequently reduce variation in a manufacturing process
- determine if the process is capable of meeting engineering design specifications

Implementation should include a process capability study and a determination of the level of its application.

**a. Process Capability.** Process capability describes the ability of a process to produce characteristics that meet the engineering design specifications. A capable process should consistently produce characteristics that meet the engineering design specifications.

A capability study should be performed to ensure that the process is capable of yielding product characteristics that meet the engineering design specifications. Two indices often used to determine capability are referred to as *Cp* and *Cpk* (the actual index names) and are described below:

(1) The *Cp index* determines if the process output is within the engineering tolerance, however, *Cp* does not indicate how close the process output is to the actual engineering target specification. This may lead to a process output that meets the engineering tolerance (e.g., +/- 0.005"), but not the engineering target specification (e.g., 1.000"). For example, if the engineering target specification was 1.000" and the tolerance was +/- 0.005", *Cp* would only indicate whether the tolerance was within +/- 0.005" of the engineering target specification.

(2) The *Cpk index* not only determines if the process output is within the engineering tolerance (e.g., +/- 0.005"), it also indicates how close the process output is to the engineering target specification (e.g., 1.000"). When determining process output capability to the engineering design specifications, *Cpk* should be used. Within the study of statistics, a minimum acceptable *Cpk* is typically defined as 1.33, which indicates a defect rate of approximately 0.0063 percent. The minimum *Cpk* value may need to be higher, indicating a lower defect rate, if the manufacturer determines that it is necessary to increase the probability of producing products within specification.

**b. Process Control.** A process is said to be in statistical control if the manufactured characteristic exhibits only random variation from the process output average. Random or natural variation occurs by chance, cannot be traced to a single cause, and can only be reduced by improving the process.  The limits of random variation can be predicted, thus the conditions producing the variation are said to be under control.

After a process is in statistical control and capable of meeting the engineering design specifications, the manufacturer should take the opportunity to evaluate whether further process improvements should be implemented for the purpose of reducing rejects and/or variation.  In some cases, reduced process variation may result in improved product reliability.

**c.  Implementing SPC Techniques.**  The following criteria describes ONE approach that may be used in the implementation of SPC techniques:

(1)  Ensure all personnel responsible for establishing, using, and analyzing SPC have been trained and have the appropriate knowledge, including proper tool and gauge use.

(2)  Establish and document the product characteristics to be measured (e.g., in a process control plan).  Additionally, the associated process at which each measurement is taken should be documented.

(3)  Ensure the measurement or evaluation method is adequate to describe the variation in the process.  Review the measurement or evaluation method to identify, eliminate, or adjust for measurement errors that may contribute to process variability.  To help ensure accurate measurement of applicable characteristics, a system for maintaining gauge repeatability and accuracy should be applied.

(4)  Review the following data elements to ensure correct application to the particular characteristic being measured:

(a)  When performing an inspection by attributes, the characteristic is classified as acceptable or unacceptable, unlike inspection by variables where the specific characteristic is measured.  The quality of the product or process is judged in terms of whether it meets specification or design requirements.  Failure of a specific characteristic to meet the specification represents a defect or nonconformance.

(b)  The data sampling frequency and sample size should be evaluated to ensure that the appropriate criteria are being applied to each characteristic.  Ensure sample sizes and measurement frequencies are statistically valid.

(c)  The use or selection of control charts (e.g., *X*-bar, *p*, *c*, etc.) should be analyzed to ensure that the correct chart for the applicable characteristic is being used.  Improper control chart application can result in data that does not accurately indicate whether the process is in control and/or capable of meeting engineering design specifications.

(d)  Collect data at the predetermined frequency during production, using appropriate data collection methods and control limits.  Record the process data on appropriate media (e.g., variable charts such as *X*-bar, *R*, and attributes charts such as *p* charts).

(e) Analyze recorded data (e.g., control charts) and investigate situations where the process is not in statistical control or does not meet minimum capability requirements. The frequency of analysis should be predetermined and identified in the applicable process procedure. Control chart analysis should be performed using recognized industry practices. Examples of analysis include in or out of control, shifts, trends, runs, and stratification. If the analysis indicates the process is out of control, the manufacturer should take any action necessary to determine the effect on product and ensure non-conformances are identified. The manufacturer should also inspect related characteristics that may have been affected by any nonconforming characteristics. Following corrective action, analyze data to determine if adjustments to the appropriate recording media, such as control charts, are necessary.

(f) Periodically review the standards used to construct the recording media (e.g., process average and control limits) and revise as necessary.

(g) Establish a record retention schedule for the recorded data.

(h) Establish and maintain an internal quality audit program to periodically monitor and evaluate all SPC processes. The audit program should include periodic process capability studies since the control charts can be in control even though the process is not capable.

**CONCLUSION.** An SQC program can be an invaluable asset to the overall quality system. Development of SPC techniques using the guidelines discussed in this document should facilitate a reduction of nonconformances, process variation, and scrap. The application of statistical sampling techniques may offer the opportunity for reduced inspection.

**Nothing Follows.**